



**6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**[FRL- 9836-4; Docket ID No. EPA-HQ-ORD-2006-0756]**

**Notice of a Public Comment Period on the Draft IRIS Carcinogenicity Assessment for Ethylene Oxide**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of public comment period.

**SUMMARY:** EPA is announcing a 45-day public comment period on the draft IRIS assessment titled, "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" (EPA/635/R-13/128a) and on the draft peer review charge questions. The draft assessment and draft peer review charge questions were prepared by the National Center for Environmental Assessment (NCEA) within the EPA Office of Research and Development (ORD). The 45-day public comment period on the draft Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide and on the draft peer review charge questions begins on the day EPA posts the draft assessment and the draft peer review charge questions on the IRIS website and ends 45 days later. EPA anticipates posting the draft assessment and draft charge questions on or around July 23, 2013. Shortly after the draft carcinogenicity assessment is posted on the IRIS website, EPA will initiate a peer review of the draft assessment, which EPA anticipates will be undertaken by the Science Advisory Board. EPA is releasing this draft carcinogenicity assessment for the purpose of public comment. This draft assessment is not final, as described in EPA's information quality

guidelines, and it does not represent and should not be construed to represent Agency policy or views.

**DATES:** The 45-day public comment period on the draft Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide and on the draft peer review charge questions begins on the day EPA posts the draft assessment and the draft peer review charge questions on the IRIS website and ends 45 days later. The draft assessment and peer review charge questions will be posted to the IRIS website at <http://www.epa.gov/IRIS>. Comments should be in writing and received by EPA within 45 days after posting the draft carcinogenicity assessment and the draft peer review charge questions on the IRIS website. EPA anticipates posting the draft assessment and draft charge questions on or around July 23, 2013.

**ADDRESSES:** The draft IRIS carcinogenicity assessment titled, “Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide” is available primarily via the Internet on the IRIS website at <http://www.epa.gov/IRIS>. A limited number of paper copies are available from the Information Management Team (Address: Information Management Team, National Center for Environmental Assessment [Mail Code: 8601P], U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: 703-347-8561; facsimile: 703-347-8691). If you request a paper copy, please provide your name, mailing address, and the draft assessment title. Comments may be submitted electronically via <http://www.regulations.gov>, by email, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions provided in the SUPPLEMENTARY INFORMATION section of this notice.

**FOR FURTHER INFORMATION CONTACT:** For information on the draft assessment, please contact Jennifer Jinot, U.S. Environmental Protection Agency, National Center for Environmental Assessment, Mail Code 8623P, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: 703-347-8597; facsimile: 703-347-8690; or email: [jinot.jennifer@epa.gov](mailto:jinot.jennifer@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

The draft IRIS assessment of the inhalation carcinogenicity of ethylene oxide was prepared by the National Center for Environmental Assessment (NCEA) within the EPA Office of Research and Development (ORD). The public has been provided an opportunity to comment on a previous external review draft of the Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide. On September 22, 2006, EPA released an external review draft “Evaluation of the Carcinogenicity of Ethylene Oxide” (EPA/635/R-06/003) for public comment. This draft was reviewed by EPA’s Science Advisory Board on January 18 and 19, 2007. The expert panel’s final report, Review of the Office of Research and Development (ORD) Draft Assessment entitled, “Evaluation of the Carcinogenicity of Ethylene Oxide” (EPA-SAB-08-004), was made available on December 21, 2007.

The draft IRIS carcinogenicity assessment titled, “Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide” (EPA/635/R-13/128a) has been revised in response to the

peer review and public comments received on the external review draft released in September 2006. This notice announces a new public comment period on the current revised draft carcinogenicity assessment in advance of an upcoming peer review and in accordance with applicable information quality guidelines. The external peer review comments and EPA responses on the previous draft assessment are summarized in Appendix H of the draft. EPA is releasing this revised draft assessment for the purposes of additional public comment and subsequent peer review. This draft assessment is not final, as described in EPA's information quality guidelines, and it does not represent and should not be construed to represent Agency policy or views.

In addition to an opportunity for public comment announced in this notice, EPA will initiate a peer review of the draft IRIS carcinogenicity assessment and will announce the details of the peer review in a separate Federal Register Notice. EPA seeks additional external peer review on how the Agency responded to the SAB panel recommendations, the exposure-response modeling of epidemiologic data, including new analyses since the 2007 external peer review, and on the adequacy, transparency, and clarity of the revised draft. The peer review will include an opportunity for the public to address the peer reviewers. EPA will announce the date, time and procedures for public participation in the peer review meeting in a separate Federal Register Notice and in an announcement on the IRIS website.

## **II. Information About IRIS**

EPA's IRIS Program is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health information for more than 550 chemical substances that can be used in human health risk assessments to support the Agency's regulatory activities and decisions to protect public health. When supported by available data, IRIS provides health effects information and toxicity values for chronic health effects (including cancer and effects other than cancer). Government agencies and others combine IRIS toxicity values with exposure information to characterize public health risks of chemical substances; this information is then used to support risk management decisions designed to protect public health.

### **III. How To Submit Comments to the Docket at <http://www.regulations.gov>**

Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2006-0756, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.
- *Email*: [ORD\\_Docket@epa.gov](mailto:ORD_Docket@epa.gov).
- *Facsimile*: 202-566-9744.
- *Mail*: Office of Environmental Information (OEI) Docket (Mail Code: 28221T), U.S.

Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460. The telephone number is 202-566-1752. If you provide comments by mail, please submit one unbound original with pages numbered consecutively, and three

copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

- *Hand Delivery:* The OEI Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202-566-1744. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by hand delivery, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

*Instructions:* Direct your comments to Docket ID No. EPA-HQ-ORD-2006-0756.

Please ensure that your comments are submitted within the specified comment period.

Comments received after the closing date will be marked “late,” and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at <http://www.regulations.gov>, including any personal information provided, unless comments include information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or email. The <http://www.regulations.gov> Web site is an “anonymous access” system, which means that EPA will not know your identity or contact

information unless you provide it in the body of your comments. If you send email comments directly to EPA without going through <http://www.regulations.gov>, your email address will be automatically captured and included as part of the comments that are placed in the public docket and made available on the Internet. If you submit electronic comments, EPA recommends that you include your name and other contact information in the body of your comments and with any disk or CD-ROM you submit. If EPA cannot read your comments due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comments. Electronic files should avoid the use of special characters and any form of encryption and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

*Docket:* All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at <http://www.regulations.gov> or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Dated: July 15, 2013.

Abdel M. Kadry,  
Acting Director, National Center for  
Environmental Assessment.

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